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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,434	06/13/2006	Olivier Gerard	FR040033US	6582

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EXAMINER	
GUPTA, VANI	
ART UNIT	PAPER NUMBER
3768	
MAIL DATE	DELIVERY MODE
06/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,434	GERARD ET AL.	
	Examiner	Art Unit	
	VANI GUPTA	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because the abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text. Correction is required. See MPEP § 608.01(b).

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1 – 11, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kusch (US 2002/0018588 A1) in view of Gilbon et al. (US 6,996,430 B1).

Regarding Claim 1, Kusch discloses a medical imaging system **(*FIGURE*)** comprising

a. an X-ray acquisition means **(*C-arm x-ray apparatus; 1*)** capable of acquiring a two-dimensional X-ray image comprising a projection of said medical instrument in accordance with a geometry of said X-ray acquisition means ([0023 - 0025];

b. an ultrasound acquisition means ***(ultrasound device; 2)*** capable of acquiring a three-dimensional ultrasound data set of medical instrument using an ultrasound probe ***(ultrasound scanner; 24)*** (pgs. [0013], [0022 – 0026]);

c. a means for providing localization ***(reference elements of navigation system; 6 and 7)*** said ultrasound probe within a referential of the X-ray acquisition means (pg. [0027 - 0028]);

d. a means capable of selecting a region of interest around an object such as a medical instrument that defines a first localization of region of interest within a

referential of said ultrasound acquisition means (***Figure, #7 and 8***; and pg. [0030]). Reference (***8***) capable of being coupled to a "subject" such as a medical device (pg. [0022], second to last sentence);

e. means for converting said first ultrasound localization within said referential of the ultrasound acquisition means into a second localization of said region of interest within said referential of the X-ray acquisition means, using said localization of the ultrasound probe (pg. [0027 – 0030]);

f. means for generating and displaying a bi-modal representation of a medical instrument in which said two-dimensional X-ray image and three-dimensional ultrasound data set are combined using second localization (***Figure, #19, 21, 25, 26;*** and pg. [0029 – 0034]; wherein "calibration" minimizes the distance, or corrects measurements of positions of objects of interest).

However, Kusch differs from Claim 1 in that Kusch does not specifically suggest that the "subject" to which reference (8) may be coupled to is a medical instrument to be guided in a patient body.

Nonetheless, Gilbon et al. teaches a "treatment-applying probe" (***fig. 1, 170;*** and col. 7, lines 51 – 60), which may be used by a dual-modality imaging system, comprising ultrasound and tomography imaging capabilities. The probe may be navigated within the body with assistance of the imaging devices (***figs. 1 and 3***; and col. 4, lines 1 – 25).

Accordingly, it would have been prima facie obvious to modify the dual-medical imaging system of Kusch to include the medical device of Gilbon et al., because an "increasing number of

medical procedures are performed by navigating a probe within a body," which is accomplished by assistance of fluoroscopic (tomographic) and ultrasound imaging (col. 1, lines 55 – 65). Gilbon et al.'s probe is designed with this in mind (col. 8, line 49 – col. 9, line 20).

Regarding claims 2 and 3, Applicant should note that the following features - wherein said means for selecting a region of interest are intended to define a reference plane in which a part of said medical instrument is included; and wherein said region of interest is a 2D ultrasound image obtained by sampling said 3D ultrasound data set over said reference plane – refer to aspects of the region of interest that do not further limit the structure of the present invention. Additionally, features of Claim 3 read on obvious design choice, as it is well known in the art to generate 3D images from a plurality of 2D images, as well as derive 2D images from 3D images (see Kusch for details/support: pg. [0025]).

Regarding Claim 4, Applicant should note that the feature wherein said region of interest is obtained by cropping a 3D ultrasound data subset, which lies behind said reference plane or by cropping a slab which is formed around said reference plane – refers to functional aspects of the present invention (or apparatus), as well as aspects of the region of interest, which do not further limit the *structure* of the apparatus. Furthermore, cited art is capable of performing actions such as image cropping (Kusch: pg. [0032 – 0033]).

Regarding claims 5, 6, 8, and 11, Applicant should note that the following features – wherein said generating means are intended to generate a volume rendered view of said region of interest within said 3D ultrasound data set; wherein said probe localization means are intended to localize an active localizer, which has been arranged on said ultrasound probe; wherein said localization means are intended to further localize said markers in a second 2D X-ray image

having a second orientation angle in said referential; and wherein the X-Ray acquisition means are intended to provide live two-dimensional X-Ray images and the ultrasound acquisition means live three-dimensional ultrasound data sets – refer to intended use of the present invention and its components and do not further limit its structure. Additionally, cited art is capable of performing such actions (see Kusch disclosure for further details). Furthermore, Kusch discusses implementing navigation means that inherently suggests obtaining "live" and/or "real-time, and "active" aforementioned data (pg. [0035]), as supported by Gilbon et al. (col. 7, line 36 – col. 8, line 5; col. 10, lines 47 – 56).

Regarding Claim 7, Applicant should note that a system as claimed in claim 1, wherein said ultrasound probe is equipped with at least three non aligned and interdependent radio-opaque markers and said localization means are intended to localize said markers in at least a first 2D X-ray image having a first orientation angle in said referential is an obvious variant of Claim 1, as it is known in the art to perform the same function multiple times and mere duplication of the essential working parts of a device involves only routine skill in the art. That is, whether one performs is using one non-aligned and interdependent radio-opaque marker, or whether one is using several non-aligned and interdependent radio-opaque markers, one of ordinary skill is still accomplishing the same goal. See *in re* St. Regis Paper Co. vs. Bemis Co., 193 USPQ 3, 11 (7th Cir. 1977). Additionally, Kusch provides structural equivalent of a non-aligned and interdependent radio-opaque marker that is capable of being localized by localization means in 2D X-ray imaging device with a first orientation angle (see rejection of Claim 1; and entire disclosure of Kusch, if necessary).

Regarding Claim 9, Kusch provides a selection means comprise means for detecting said medical instrument within said region of interest of the 3D ultrasound data set (see rejection of Claim 1). With respect to the feature, said generating means are intended to give to the points of the detected medical instrument in said bimodal representation the X-ray intensity values of the corresponding points in the 2D X-Ray image, Applicant should note that this feature refers to intended use of the generating means of the present invention and does not further limit its structure.

Regarding Claim 10, Gilbon et al. teaches a means for segmenting a wall tissue region in the 3D ultrasound data set (col. 6, lines 53 – 65; and col. 11, lines 27 – 35), wherein "cross-sectional images" are equivalent of segmented regions. With respect to the feature "generating means are intended to give to the points belonging to said wall tissue region the ultrasound intensity values of the corresponding points of said region of interest," Applicant should note that it refers to the intended use of the generating means and does not further limit the structure of the apparatus. Furthermore, Gilbon et al. is capable of performing this function (col. 10, lines 14 – 41).

Regarding Claim 13, Kusch presents a means for compensating a motion between a current three-dimensional ultrasound data set acquired at a current time and a previous three-dimensional ultrasound data set acquired at a previous time (pgs. [0030 – 0033]).

Regarding Claim 14, Kusch in view of Gilbon et al. teaches a method of guiding a medical instrument in a patient body, comprising the steps of:

a. acquiring a two-dimensional X-ray image of said medical instrument using an X-ray acquisition system; acquiring a three-dimensional ultrasound data set of said medical instrument using said ultrasound probe and an ultrasound acquisition system; and localizing said ultrasound probe in a referential of said X-ray acquisition system (see Kusch and rejection of Claim 1);

b. selecting a region of interest of said medical instrument within said 3D ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition system (see Kusch in view of Gilbon et al. and rejection of Claim 1);

c. converting said first localization within said referential of said ultrasound acquisition system into a second X-Ray localization within said referential of the X-ray acquisition system (see Kusch and rejection of Claim 1); and

d. generating and displaying a bimodal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization (Kusch – combined images with reference (8) registered with image – pgs. [0030] and [0034]; and Gilbon et al., wherein reference is coupled to medical device and imaging of device itself - col. 7, lines 51 – 52).

2. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kusch (US 2002/0018588 A1) in view of Gilbon et al. (US 6,996,430 B1) as applied to claims 1 and 11 above, and further in view of Cline et al. (US 5,368,032).

Regarding Claim 12, Kusch in view of Gilbon et al. discloses the apparatus as dicussed in the rejections of claims 1 and 11. Kusch also explains that the position of the ultrasound probe is identified at times of the ultrasound imaging (pg. [0027]).

However, Kusch in view of Gilbon et al. differs from Claim 12 in that Kusch in view of Gilbon et al. does not specifically suggest controlling means for periodically triggering the ultrasound imaging means, and therefore trigger probe localization means.

Nonetheless, Cline et al. teaches triggering image acquisition means via a footswitch (***fig. 1, 79***) through a controller ***(75).*** Imaging is accomplished as a means to track a device (col. 3, lines 36 – 60).

Accordingly, it would have been prima facie obvious to modify the ultrasound imaging means of Kusch in view of Gilbon et al. to include the image triggering means of Cline et al., so that the system operator may more easily switch (or "toggle") among preset imaging parameters (col. 4, lines 32 – 37).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. ***Strommer et al. (US 7,505,809 B2)*** for method and system for first medical positioning system for detecting a first position and orientation of the body of a patient, a second medical positioning system for detecting a second position and orientation of the body, and registering a first image with a second image relative to the body of a patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Friday (8:30 am - 5:30 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-2083. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768